PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
DANIEL E. ALTMAN
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET, 14TH FLOOR
IRVINE, CA 92614

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference ANVIL-029VPC	Date of mailing *(day/month/year)* 13 OCT 2010 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 10/40962	International filing date *(day/month/year)* 02 July 2010 (02.07.2010)
Applicant TRYTON MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Lee W. Young PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2010)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ANVIL-029VPC	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 10/40962	International filing date *(day/month/year)* 02 July 2010 (02.07.2010)	(Earliest) Priority Date *(day/month/year)* 02 July 2009 (02.07.2009)
Applicant TRYTON MEDICAL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 2N

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 10/40962

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/90
USPC - 623/1.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
623/1.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC: A61F2/00, 2/02, 2/04, 2/06, 2/82, 2/86, 2/94
USPC: 623/1.1, 1.11, 1.12, 1.16, 1.17, 1.35

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB,USPT,EPAB,JPAB), Google Scholar: Prosthesis, implant, ostium, bifurcation, vascular, arteries, blood, frond, filament, stent, catheter, expansible, expandable, extendable, undulating, dual serpentine section.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0163999 A1 (Kaplan et al.) 25 June 2009 (25.06.2009), abstract, para [0014]-[0017], [0024], [0037], [0039]-[0040], [0043]-[0044], [0047]-[0048], [0051], [0056], [0062], [0065], [0072], [0074]-[0076], [0100]-[0102], [0105], [0111]-[0117], [0126]-[0130], [0139], fig. 1, figs. 2A-2F, figs. 3A-3B, fig. 5, figs. 12D-12F, fig. 14E	1-4, 6-7, 15, 18-19, 22-37, 40
---		---
Y		5, 8-14, 16-17, 20-21, 38-39, 41-46
Y	US 2008/0294240 A1 (Casey) 27 November 2008 (27.11.2008), para [0050]	5
Y	US 2007/0288082 A1 (Williams) 13 December 2007 (13.12.2007), para [0082]-[0083]	8-14, 16-17, 20-21, 38-39
Y	US 2007/0276460 A1 (Davis et al.) 29 November 2007 (29.11.2007), para [0118], [0158]-[0159], [0163]-[0164], fig. 2G	9-14, 16-17, 20-21, 38-39, 41-46

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2010 (30.09.2010)	13 OCT 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL E. ALTMAN
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET, 14TH FLOOR
IRVINE, CA 92614

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	13 OCT 2010
Applicant's or agent's file reference ANVIL-029VPC	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 10/40962	02 July 2010 (02.07.2010)	02 July 2009 (02.07.2009)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/90 (2010.01)
USPC - 623/1.15

Applicant TRYTON MEDICAL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	30 September 2010 (30.09.2010)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-21, 23-36, 38-46	YES
	Claims	22, 37	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-46	NO
Industrial applicability (IA)	Claims	1-46	YES
	Claims	None	NO

2. Citations and explanations:

Claims 22, 37 lack novelty under PCT Article 33(2) as being anticipated by US 2009/0163999 A1 to Kaplan et al. (hereinafter Kaplan).

As per claim 22, Kaplan discloses a prosthesis for placement at an ostium opening from a main body lumen to a branch body lumen (abstract, para [0014]), the prosthesis comprising: a radially expansible support having a plurality of proximal apices, the support configured to be deployed in at least a portion of a body lumen adjacent the ostium opening (abstract, para [0014], figs. 1, 2A); a transition portion coupled with at least one of the proximal apices on the support (para [0037], para [0076], fig. 2A: transition zone (60), a plurality of proximal apices points (63) on the support) and having a distal section with four side-by-side filaments and a proximal section having two side-by-side filaments (para [0076]; fig. 2A: four curving elements (66A, 66B, 66c, and 66D) at the distal end of the transition zone (60), which reduce in number to two elements (66A and 66D) at proximal section); a plurality of frond sections extending between the transition portion and a proximal end (para [0076], fig. 2A: fronds (16)), each of the frond sections comprising a single filament section having a single filament extending axially from the proximal end of the frond sections toward the transition portion (para [0076], fig. 2A: fronds (16)), the frond sections configured to be deformably deployed in at least a portion of a body lumen adjacent the ostium (para [0076]); a circumferential link connected to at least one of the proximal ends of the frond sections (para [0112], para [0116], fig. 2F: circumferential link (120), attachment points (126) and (128) between the circumferential link and the fronds).

As per claim 37, Kaplan discloses a prosthesis for placement at an opening from a main body lumen to a branch body lumen (abstract, para [0014]), the prosthesis comprising: a radially expansible support adapted to provide a radial force to support a body lumen on a first side of the opening (abstract, para [0014], para [0062]); at least two elongate, flexible fronds each having a first end, a second end (para [0111], figs. 2A-2E), and an axially extending undulating portion (para [0102]), at least a portion of the undulating portion comprising a plurality of spaced apart filaments (para [0065], para [0102], fig. 2D: a plurality of connectors (84)), the fronds extending from an end of the support and configured to be positioned across the ostium (para [0040], para [0043]); at least one circumferential link being connected to the second ends of at least one of the fronds (para [0017]), the circumferential link spaced axially apart from the support by the fronds (para [0017]); and a plurality of elongate gaps in between adjacent fronds defined by single filament sections of the fronds (para [0048], para [0130]), the gaps configured to facilitate crossing of a second stent therethrough (para [0139], figs. 12D-12F: the first stent or stent (10) and the second stent or the main vessel stent (150)) when the support is positioned on the first side of the opening and the circumferential link is positioned on a second side of the opening (para [0129], fig. 14E: the support (52) and the circumferential link (120)).

Claims 1-4, 6-7, 15, 18-19, 23-36, 40 lack inventive step under PCT Article 33(3) as being obvious over Kaplan.

As per claim 1, Kaplan discloses a prosthesis for placement at an opening from a main body lumen to a branch body lumen (abstract, para [0014]), the prosthesis comprising: a radially expansible support configured to be deployed in at least a portion of the branch body lumen (abstract, para [0014]); a plurality of fronds extending from an end of the support, the fronds configured to be positioned across the ostium opening and into the main body lumen (abstract, para [0014], [0051], [0072], [0126]); a plurality of elongate side wall spaces in between adjacent fronds, the spaces configured to receive a stent deployment device therethrough (para [0024], [0130], figs. 3A-3B: an embodiments prosthesis/delivery system (205), fronds (220), axial gaps, space, or splits (230), delivery balloon (241)); and a circumferential link connected to the fronds, the circumferential link spaced apart from the support by the fronds, the circumferential link comprising a first portion located adjacent to proximal ends of the fronds (para [0111]-[0116], fig. 2F: circumferential link (120)), however, does not specifically disclose wherein the circumferential link comprises a second portion located on a proximal side of the first portion, the second portion configured to surround a space that can be occupied by at least a portion of an expansion device. Kaplan discloses wherein at least one circumferential link connects on proximal side of the prosthesis (para [0017]), and the method may comprise a step of positioning an expansion device such as an inflatable balloon in the circumferential link to deform it such that the circumferential link conforms to at least a portion of the wall of the main lumen(para [0016]), and the circumferential link will assist in maintaining the crimped profile of the fronds on an expansion device such as a balloon (para [0112]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein more than one circumferential links are used, where the second portion of circumferential link is located on a proximal side of the first portion, the second portion configured to surround a space that can be occupied by at least a portion of an expansion device, to provide a secure expandable connection between a proximal portion of the prosthesis and a delivery device.

----------See Supplemental Sheets-----

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Box V.2: Citations and Explanations:

As per claim 2, Kaplan discloses the prosthesis of Claim 1, Kaplan further discloses the first portion comprises an undulating circumferentially expandable structure (para [0116], fig. 2F: circumferential link (120)).

As per claim 3, Kaplan discloses the prosthesis of Claim 1, Kaplan further discloses the first portion comprises a plurality of peaks and valleys that are axially arranged (para [0116], fig. 2F: circumferential link (120), sinusoidal shape (122)).

As per claim 4, Kaplan discloses the prosthesis of Claim 3, Kaplan further discloses alternating peaks of the first portion are coupled with the proximal ends of the fronds (para [0116], fig. 2F: circumferential link (120), attachment point (126 and 128)).

As per claim 6, Kaplan discloses the prosthesis of Claim 1, however, does not specifically disclose wherein the second portion comprises a circumferentially expandable structure. Kaplan discloses wherein the circumferential link is expandable or enlargeable in a circumferential direction (para [0116]). It would have been obvious to one of ordinary skill in the art to use the teaching of Kaplan, wherein the second portion of the circumferential link comprises a circumferentially expandable structure to assist in maintaining the spacing of the fronds to facilitate advancement of the main vessel stent therethrough.

As per claim 7, Kaplan discloses the prosthesis of Claim 1, however, does not specifically disclose the second portion has an undulating configuration. Kaplan discloses wherein the circumferential link is provided with an undulating configuration (para [0116], fig. 2F: circumferential link (120)). It would have been obvious to one of ordinary skill in the art to use the teaching of Kaplan, wherein the second portion of the circumferential link can have an undulating configuration to optimize the radial expansion of the circumferential link.

As per claim 15, Kaplan discloses a prosthesis for placement at an opening from a main body lumen to a branch body lumen (abstract, para [0014]), the prosthesis comprising: a radially expansible support configured to be deployed in at least a portion of the branch body lumen (abstract, para [0014]), the support adapted to provide a radial force to support a first body lumen (para [0062]); a plurality of fronds extending from an end of the support, the fronds configured to be positioned across the ostium opening and into a second body lumen (abstract, para [0014], [0051], [0072], [0126]); and a circumferential link connected to at least one of the fronds, the circumferential link spaced apart from the support by the at least one frond, wherein the circumferential link comprises a frond engagement portion adjacent to proximal ends of the fronds (para [0111]-[0116], fig. 2F: circumferential link (120)), however, does not specifically disclose wherein the circumferential link comprises a catheter securement portion located on a proximal side of the frond engagement portion. Kaplan discloses wherein at least one circumferential link connects on proximal of the fronds (para [0017]), and the method comprises a prosthesis and a delivery system (para [0057], fig. 1: prosthesis (10) and a delivery catheter (30)), wherein delivery system comprises a delivery catheter, at least a portion of catheter is positioned in the fronds, and the system also includes a retainer such as cuff for capturing the fronds to prevent them from divaricating from the expandable member as the catheter is advanced through a patient's vasculature (para [0047], fig. 5: cuff (250)). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the circumferential link comprises a catheter securement portion located on a proximal side of the frond engagement portion to provide a secure connection between a proximal portion of the prosthesis and the delivery catheter to prevent the fronds from divaricating from the catheter.

----------See Supplemental Sheets-----

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 18, Kaplan discloses a prosthesis for placement at an ostium opening from a first body lumen to a second body lumen (abstract, para [0014]), the prosthesis comprising: a radially expansible support configured to be deployed in at least a portion of the first body lumen (abstract, para [0014]); at least one frond extending from an end of the support, the at least one frond configured to be positioned across the ostium opening (abstract, para [0014], [0051], [0072], [0126]); and a circumferential link connected to the at least one frond, the circumferential link spaced apart from the support by the at least one frond (para [0111]-[0116], fig. 2F: circumferential link (120)), however, does not specifically disclose wherein the circumferential link comprises a catheter securement portion located adjacent to an end of the at least one frond that is spaced apart from the support and a frond engagement portion located adjacent the end of the at least one frond that is spaced apart from the support, the frond engagement portion located between the catheter securement portion and the support, the catheter securement portion configured to surround a space that can be occupied by at least a portion of an expansion device. Kaplan discloses wherein at least one circumferential link connects at least a first and a second frond at the proximal end, the circumferential link spaced axially apart from the support (para [0017]), and the method comprises a prosthesis and a delivery system (para [0057], fig. 1: prosthesis (10) and a delivery catheter (30)), and delivery system comprises a delivery catheter having a catheter balloon or other expandable member and a prosthesis carried over the expandable member, and at least a portion of catheter is positioned in the fronds, and the system also includes a retainer such as cuff for capturing the fronds to prevent them from divaricating from the expandable member as the catheter is advanced through a patient's vasculature (para [0047], fig. 5: cuff (250)), and wherein the position of a circumferential link at the proximal of the fronds can provide sufficient holding force to omit need to the cuff (para [0112]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein circumferential link comprises a catheter securement portion located adjacent to an end of the at least one frond that is spaced apart from the support and a frond engagement portion located adjacent the end of the at least one frond that is spaced apart from the support, the frond engagement portion located between the catheter securement portion and the support, the catheter securement portion configured to surround a space that can be occupied by at least a portion of an expansion device to provide a secure connection between a proximal portion of the prosthesis and the delivery catheter and to prevent the fronds from divaricating from the catheter.

In addition, Kaplan does not specifically disclose wherein the prosthesis is configured to receive a second prosthesis through the space surrounded by the catheter securement portion such that when the second prosthesis is deployed the at least one frond is entrapped between a vessel wall and the second prosthesis. Kaplan discloses wherein the fronds may be fully expanded to open the luminal passage through the main branch lumen and such open main vessel lumen permits optional placement of a second prosthesis within the main branch lumen using conventional techniques (para [0039], para [0126]-[0128]), and wherein the main vessel stent is deployed to entrap the fronds against the vessel wall (para [0128]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the prosthesis is configured to receive a second prosthesis through the space surrounded by the catheter securement portion such that when the second prosthesis is deployed the at least one frond is entrapped between a vessel wall and the second prosthesis to provide sufficient radial support as well as adequate surface area coverage to securely anchor the prostheses in the side branches.

As per claim 19, Kaplan discloses the prosthesis of Claim 18, Kaplan further discloses wherein the at least one frond is configured to be disposed in the second body lumen in an upstream or downstream direction from the ostium when deployed (abstract, para [0126]).

As per claim 23, Kaplan discloses the prosthesis of Claim 22, Kaplan further discloses the support comprises a closed cell structure (para [0074], fig. 2A: a plurality of cells (57), figs. 2E-2F: a plurality of cells including a distal apex and a proximal apex correspond to crests and troughs of adjacent circumferentially oriented sinusoidal members, and two lateral deformable N-shaped member on stent section (52)).

As per claim 24, Kaplan discloses the prosthesis of Claim 23, Kaplan further discloses each of the cells comprise lateral members adapted to enhance the flexibility of the support by permitting localized axial expansion or compression within the support. (para [0074], fig. 2A: a plurality of axially extending struts (61), figs. 2E-2F: a plurality of lateral deformable N-shaped member on stent section (52))

As per claim 25, Kaplan discloses the prosthesis of Claim 23, Kaplan further discloses each of the cells comprises N-shaped connector disposed on opposite lateral sides of the cells (para [0074]; figs. 2E-2F: Two N-shaped connector on both lateral side of each cell on stent section (52)).

As per claim 26, Kaplan discloses the prosthesis of Claim 22, Kaplan further discloses wherein the support comprises an open cell structure (para [0074], fig. 2A: open cells (57) and (59) wherein cells comprising some picks and troughs of adjacent circumferentially oriented sinusoidal or undulating members (56) and (58); the support in figs. 2B-2D comprise these tape of cells).

As per claim 27, Kaplan discloses the prosthesis of Claim 26, Kaplan further discloses the support comprises a first circumferentially oriented undulating member and a second circumferentially oriented undulating member (para [0074], figs. 2A-2F: circumferentially undulating or serpentine members (56) and (58)), the second circumferentially oriented undulating member disposed proximally of the first circumferentially oriented undulating member (para [0074], figs. 2A-2F: circumferentially undulating or serpentine members (56) and (58)), the support further comprising a plurality of longitudinal interconnecting members extending from distal apices of the second circumferentially oriented undulating member to distal spices of the first circumferentially oriented undulating member (para [0074], figs. 2A -2F: a plurality of axially extending struts (61)).

------See Supplemental Sheets-----

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 28, Kaplan discloses the prosthesis of Claim 27, however, does not specifically disclose wherein the longitudinal interconnecting members comprise at least one circumferentially oriented undulation. Kaplan discloses wherein, in a different embodiment, the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending struts (61) (fig. 2A) or N-shaped connector elements (figs. 2E-2F) (para [0074]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the longitudinal interconnecting members can have a specific shape, comprises at least one circumferentially oriented undulation to allow axial movement of the adjacent undulating member.

As per claim 29, Kaplan discloses the prosthesis of Claim 26, however, does not specifically disclose wherein the support comprises a plurality of circumferential bands, the circumferential bands being coupled at alternating undulating positions. Kaplan discloses wherein, in a different embodiment, the support can be shaped in form of helical spiral or zig-zag series of members, connected by a plurality of proximal apexes and a plurality of distal apexes, rolled into a cylindrical configuration (para [0062]), and wherein the support comprises a plurality of circumferential serpentine or undulating members, whereas these members are connected at alternating undulating positions as shown in figs. 2A-2F (para [0074]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the circumferential undulating members in the support can be substituted by the circumferential bands wherein the circumferential bands being coupled at alternating undulating positions to provide a greater degree of flexibility of support wall.

As per claim 30, Kaplan discloses the prosthesis of Claim 27, however, does not specifically disclose wherein the prosthesis further comprises a linking member linking proximal apices of a first circumferential bands and distal apices of a second circumferential band, the second circumferential band being located adjacent and proximal to the first circumferential band. Kaplan discloses wherein the second circumferential undulating member is located adjacent and proximal to the first circumferential undulating member (para [0074], figs.2A-2F), and the connector members such as struts (61) in fig.2A link the distal apices of distal apices of the second circumferential undulating member to distal apices of the first circumferential undulating member, or the proximal apices of distal apices of the second circumferential undulating member to proximal apices of the first circumferential undulating member, or like the connecter members such as shown in fig. 2D link the distal apices of distal apices of the second circumferential oriented undulating member to proximal apices of the first circumferential undulating member (para [0074]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the circumferential undulating members in the support can be substituted by the circumferential bands wherein the second circumferential band being located adjacent and proximal to the first circumferential band to provide a radially expandable wall for the support. It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the linking members connect proximal apices of a first circumferential bands and distal apices of a second circumferential band to enhance stability of the support wall and to optimize axial movement of the adjacent circumferential bands.

As per claim 31, Kaplan discloses the prosthesis of Claim 30, however, does not specifically disclose wherein two unconnected apices are disposed circumferentially between adjacent linking members. Kaplan discloses wherein a wide variety of conventional stent structures and patterns may be equally useful as the support section of the prostheses such as examples shown in figs. 2A-2F that include one unconnected apices disposed circumferentially between adjacent connecting members (para [0074]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein two unconnected apices are disposed circumferentially between adjacent linking members to optimize the flexibility, expandability, and stability of the wall of the support for different surgical use.

As per claim 32, Kaplan discloses the prosthesis of Claim 22, Kaplan further discloses the proximal section of the transition portion comprises a dual serpentine section (para [0100]-[0102], fig. 2D : a dual serpentine structure (82)).

As per claim 33, Kaplan discloses the prosthesis of Claim 32, however, does not specifically disclose wherein the dual serpentine section is configured for transitioning from a bifurcation with a high take-off angle. Kaplan discloses wherein fronds roots (the dual serpentine structure in transition section) may be optimized for particular bifurcation angles and orientations, such as by making the fronds for positioning closer to the "toe" of the bifurcation longer than the fronds for positioning closer to the carina or "heel" of the bifurcation (para [0056]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan wherein the dual serpentine section can be configured for transitioning from a bifurcation with a high take-off angle to better adapt to the specific bifurcation geometry.

As per claim 34, Kaplan discloses the prosthesis of Claim 32, however, does not specifically disclose wherein the dual serpentine section is configured for transitioning from a bifurcation with a low take-off angle. Kaplan discloses wherein fronds roots (the dual serpentine structure in transition section) may be optimized for particular bifurcation angles and orientations, such as by making the fronds for positioning closer to the "toe" of the bifurcation longer than the fronds for positioning closer to the carina or "heel" of the bifurcation (para [0056]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan wherein the dual serpentine section can be configured for transitioning from a bifurcation with a low take-off angle to better adapt to the specific bifurcation geometry.

-----See Supplemental Sheets-----

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 35, Kaplan discloses the prosthesis of Claim 32, however, does not specifically disclose wherein the dual serpentine section extends over a length that is less than 1/3 the length of the single filament of the frond section. Kaplan further discloses wherein it may be desirable to provide fronds having different lengths (para [0045]), and the axial length of each frond can vary from at least about 10% to 75% or more of the length of the overall prosthesis (para [102]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the dual serpentine section extends over a length that can be less than 1/3 the length of the single filament of the frond section to optimize flexibility of the fronds.

As per claim 36, Kaplan discloses the prosthesis of Claim 32, however, does not specifically disclose wherein the dual serpentine section extends over a length that is 1/2 or more than the length of the single filament of the frond section. Kaplan further discloses wherein it may be desirable to provide fronds having different lengths (para [0045]), and the axial length of each frond can vary from at least about 10% to 75% or more of the length of the overall prosthesis (para [102]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the dual serpentine section extends over a length that can be 1/2 or more than the length of the single filament of the frond section to optimize flexibility of the fronds.

As per claim 40, Kaplan discloses the prosthesis of Claim 37, however, does not specifically disclose wherein the single filament portion is configured with an undulating structure wherein the maximum angle of approach thereof does not exceed 45 degrees. Kaplan discloses wherein fronds may be optimized for particular bifurcation angles and orientations (para [0056]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the single filament portion of the frond can be configured with an undulating structure wherein the maximum angle of approach thereof does not exceed 45 degrees to prevent stress concentration there and reduce the effect of impact.

Claim 5 lacks inventive step under PCT Article 33(3) as being obvious over Kaplan in view of US 2008/0294240 A1 (Casey).

As per claim 5, Kaplan discloses the prosthesis of Claim 1, however, does not specifically disclose the first portion is configured to absorb torque applied from the fronds to isolate mechanically a distal portion of the second portion from the torque. Casey discloses wherein the connectors with shapes reminiscent of the letters .N. or .W. can absorb the torque (para [0050]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Casey, wherein since the first portion comprises .W. shape element can absorb torque applied from the fronds to isolate mechanically the distal portion of the second portion from the torque to make a secure connection in the distal portion of the second portion with a delivery device.

Claim 8 lacks inventive step under PCT Article 33(3) as being obvious over Kaplan in view of US 2007/0288082 A1 (Williams).

As per claim 8, Kaplan discloses the prosthesis of Claim 7, however, does not specifically disclose wherein the undulating pattern is out-of-phase with an undulating pattern of the first portion. Kaplan discloses wherein the circumferential link has an undulating configuration (para [0116], fig. 2F: circumferential link (120)). Williams discloses wherein the stent comprises a plurality of undulating rings that are connected to each other by links, and the links can be a weld, laser fusion, or similar connection and are particularly suited to stent patterns that are out of phase (para [0082]-[0083]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Williams, wherein the second portion of the circumferential link with the undulating pattern (the catheter securement portion) can be out-of-phase with an undulating pattern of the first portion (the frond engagement portion) to enhance expandability of the circumferential link structure.

Claims 41-46 lack inventive step under PCT Article 33(3) as being obvious over Kaplan in view of US 2007/0276460 A1 to Davis et al. (hereinafter Davis).

As per claim 41, Kaplan discloses prosthesis for placement at an ostium opening at a vascular bifurcation (abstract, para [0014]), the prosthesis comprising: a radially expansible support having a plurality of apices disposed at an end of the support, the support configured to be deployed in a vascular segment adjacent to a bifurcation (abstract, para [0014]); at least one frond extending axially from an end of the support (para [0037]), the frond including a first end with a transition portion attached to apices on the support and a second end (para [0111], figs. 2A-2E); and the fronds configured to be deployed in a vascular segment adjacent to a bifurcation (para [0014]-[0015]); however, does not specifically disclose wherein the fronds comprise a section with a single filament extending between the transition portion to the second end of the fronds. Kaplan discloses wherein the single frond may extend axially from the branch vessel support, and the single frond (or two or three or more fronds) may extend in a helical or spiral pattern (para [0044]). Davis discloses wherein the frond section comprises a single frond, in the form of a single wire or filament, which extends in a spiral configuration about the longitudinal axis of the prosthesis (para [0159]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Davis, wherein the fronds can comprise a section with a single filament extending between the transition portion to the second end of the fronds to enhance flexibility and expandability of the structure. In addition, Kaplan does not specifically disclose wherein a circumferential link connects to the single filament at the second end of the frond. Kaplan discloses wherein (para [0112], para [0116], fig. 2F: circumferential link (120), attachment points (126) and (128) between the circumferential link and the fronds). Davis discloses wherein the proximal end of the frond section with single filament is provided with a circumferential link (para [0158]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Davis, wherein the circumferential link can connect to the single filament at the second end of the frond to enhance stability of the fronds.

-----See Supplemental Sheets-----

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 42, Kaplan and Davis disclose the prosthesis of Claim 41, Kaplan further discloses wherein at least one of the tubular distal portion and the fronds comprise drug containing portions disposed thereon (para [0017], para [0105]).

As per claim 43, Kaplan discloses a prosthesis for placement across an ostium at a vascular bifurcation (abstract, para [0014]), the prosthesis comprising: a radially expansible support having a first end, a second, and length therebetween configured to be deployed in and provide scaffolding in a vascular segment adjacent to the ostium(abstract, para [0014] , figs. 1, 2A); at least one frond extending from one of the first or second ends of the support, the fronds having a first end with a transition portion and a second end (para [0037], fig. 2A), the transition portion attached to one of the first or second ends of support (para [0037], fig. 2A), the transition portion having a plurality of support members (para [0076], figs. 2B-2F); and the fronds configured to be deployed within a vascular segment adjacent to the ostium (para [0014]-[0015]); and at least one of the radially expansible support and the frond comprise drug containing portions disposed thereon (para [0017], para [0105]); however, does not specifically disclose wherein the frond comprises a section having a single filament extending between the transition portion and the proximal end of the frond. Kaplan discloses the single frond may extend axially from the branch vessel support, and the single frond (or two or three or more fronds) may extend in a helical or spiral pattern (para [0044]). Davis discloses wherein the frond section comprises a single frond, in the form of a single wire or filament, which extends in a spiral configuration about the longitudinal axis of the prosthesis (para [0159]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Davis, wherein the frond can comprise a section having a single filament extending between the transition portion and the proximal end of the frond to enhance flexibility and expandability of the structure. In addition, Kaplan does not specifically disclose wherein a circumferential link connects to the single filament of the at least one frond at the second end of the frond. Kaplan discloses wherein (para [0112], para [0116], fig. 2F: circumferential link (120), attachment points (126) and (128) between the circumferential link and the fronds). Davis discloses wherein the proximal end of the frond section with single filament is provided with a circumferential link (para [0158]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Davis, wherein the circumferential link can connect to the single filament of the at least one frond at the second end of the frond to enhance stability of the fronds.

As per claim 44, Kaplan and Davis disclose the prosthesis of Claim 43, Davis further discloses the transition portion comprises depots configured to retain a drug (para [0118]).

As per claim 45, Kaplan and Davis disclose the prosthesis of Claim 43, however, do not specifically disclose wherein the single filament comprises a serpentine portion. Kaplan discloses wherein the single frond may extend axially from the branch vessel support, and the single frond (or two or three or more fronds) may extend in a helical or spiral pattern (para [0044]). Davis discloses wherein the frond section comprises a single frond, in the form of a single wire or filament, which extends in a spiral configuration about the longitudinal axis of the prosthesis (para [0159]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Davis, wherein the single filament of the front section can comprise a serpentine portion to enhance flexibility and expandability of the frond section.

As per claim 46, Kaplan and Davis disclose the prosthesis of Claim 43, however, do not specifically disclose wherein the transition portion comprises first and second straight members joined at one end and coupled at the opposite end with different apices of the support. Kaplan discloses wherein the prosthesis comprises a transition zone between the support and the frond (para [0037]), and in one embodiment the transition portion comprises first and second curving members joined at one end to the frond and coupled at the opposite end at one apices of the support (para [0076], fig. 2A: transition portion: (60)), and the wall patterns can be varied widely as desired to provide additional coverage, transition in axial stiffness, and accommodate various side branch angles with respect to the main vessel long axis (para [0075]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the transition portion comprises first and second straight members joined at one end and coupled at the opposite end with different apices of the support to optimize the flexibility of the structure and to form drug containers on transition portion.

Claims 9-14, 16-17, 20-21, 38-39 lack inventive step under PCT Article 33(3) as being obvious over Kaplan, Williams, and Davis.

As per claim 9, Kaplan discloses the prosthesis of Claim 1, however, do not specifically disclose wherein the circumferential link further comprising an axial coupling member disposed between the first portion and the second portion. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A) or N-shaped connector elements (figs. 2E-2F) (para [0074]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). Williams discloses wherein the stent comprises a plurality of undulating rings, and the rings can be attached to each other by links having various shapes, including straight links or non-linear links having curved portions (para [0082]-[0083]). Davis discloses wherein a plurality of connectors (61) is provided to connect the frond (16) to the support section (52) (para [0163], fig. 2G), and the circumferential link (120) may be connected to the frond (16) in a variety of ways, such as by providing one or more connectors (121) (para [0164], fig. 2G). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan, Williams, and Davis, wherein the connection between two parts of circumferential link can be provided using an axially extending member disposed therebetween, like the connection structure in the support to make a secure connection to enhance stability of the Structure.

-----See Supplemental Sheets-----

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 10, Kaplan, Williams, and Davis disclose the prosthesis of Claim 9, however, do not specifically disclose wherein the axial coupling member provides sufficient connection between the first portion and the second portion to resist premature expansion of a proximal portion of the first portion from a low profile configuration. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A) to provide additional axial stiffness (para [0075]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the axial coupling member can provide sufficient connection between the first portion and the second portion to resist premature expansion of a proximal portion of the first portion from a low profile configuration to enhance stability of the proximal of the prosthesis.

As per claim 11, Kaplan, Williams, and Davis disclose the prosthesis of Claim 9, however, do not specifically disclose wherein the axial coupling member comprises a plurality of axially extending connectors. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A) to provide additional axial stiffness (para [0075]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the axial coupling member can comprise a plurality of axially extending connectors to enhance mechanical stiffness of two portions of the circumferential link.

As per claim 12, Kaplan, Williams, and Davis disclose the prosthesis of Claim 11, however, do not specifically disclose wherein each connector connects a peak of the second portion with a valley of the first portion. Kaplan discloses wherein the connector members such as the axially extending member (61) in fig.2A link the distal apices of distal apices of the second circumferential undulating member to distal spices of the first circumferential undulating member, or the proximal apices of distal apices of the second circumferential undulating member to proximal spices of the first circumferential undulating member, or like the connecter members such as shown in fig. 2D link the distal apices of distal apices of the second circumferential oriented undulating member to proximal apices of the first circumferential undulating member (para [0074]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein each connector can connect a peak of the second portion with a valley of the first portion to make a sufficient connection to enhance stability of two portions of the circumferential link.

As per claim 13, Kaplan, Williams, and Davis disclose the prosthesis of Claim 9, however, do not specifically disclose wherein the axial coupling member is a generally straight member. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein the axial coupling member in the circumferential link can be a generally straight member to enhance axial stiffness of the circumferential link.

As per claim 14, Kaplan, Williams, and Davis disclose the prosthesis of Claim 9, however, do not specifically disclose wherein the axial coupling member has one or more undulations. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending struts (61) (fig. 2A) or N-shaped connector elements (figs. 2E-2F) (para [0074]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). Williams discloses wherein the stent comprises a plurality of undulating rings, and the rings can be attached to each other by links having various shapes, including straight links or non-linear links having curved portions (para [0082]-[0083]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Williams, wherein the axial coupling member has one or more undulations to optimize mechanical isolation of the circumferential link.

As per claim 16, Kaplan discloses the prosthesis of Claim 15, however, does not specifically disclose wherein the circumferential link further comprises an axially extending member disposed between the frond engagement portion and the catheter securement portion. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A) or N-shaped connector elements (figs. 2E-2F) (para [0074]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). Williams discloses wherein the stent comprises a plurality of undulating rings, and the rings can be attached to each other by links having various shapes, including straight links or non-linear links having curved portions (para [0082]-[0083]). Davis discloses wherein a plurality of connectors (61) is provided to connect the frond (16) to the support section (52) (para [0163], fig. 2G), and the circumferential link (120) may be connected to the frond (16) in a variety of ways, such as by providing one or more connectors (121) (para [0164], fig. 2G). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan, Williams, and Davis, wherein the circumferential link can comprise an axially extending member disposed between the frond engagement portion and the catheter securement portion, like the connection structure in the support, to make a secure connection to enhance stability of the Structure.

-----See Supplemental Sheets-----

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 10/40962

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 17, Kaplan, Williams, and Davis disclose the prosthesis of Claim 16, however, do not specifically disclose wherein the frond engagement portion and the catheter securement portion are undulating portions that extend circumferentially and out-of-phase with each other. Kaplan discloses wherein the circumferential link has an undulating configuration (para [0116], fig. 2F: circumferential link (120)). Williams discloses wherein the stent comprises a plurality of undulating rings that are connected each other by links, and the links are not limited by any particular length or shape and can be a weld, laser fusion, or similar connection, and welds or laser fusion processes are particularly suited to stent patterns that are out of phase (para [0082]-[0083]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Williams, wherein two portion of the circumferential link (the frond engagement portion and the catheter securement portion) can have an undulating pattern that is out-of-phase with a generally sinusoidal pattern to enhance expandability of the circumferential link structure. In addition, Kaplan does not specifically disclose wherein the axially extending member connects a trough of the frond engagement portion with a peak of the catheter securement portion. Kaplan discloses wherein the connector members such as the axially extending member (61) in fig.2A link the distal apices of distal apices of the second circumferential undulating member to distal spices of the first circumferential undulating member, or the proximal apices of distal apices of the second circumferential undulating member to proximal spices of the first circumferential undulating member, or like the connecter members such as shown in fig. 2D link the distal apices of distal apices of the second circumferential oriented undulating member to proximal apices of the first circumferential undulating member (para [0074]) and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the axially extending member can connect a trough of the frond engagement portion with a peak of the catheter securement portion, similar to the connecting structure in the support section, to provide proper connection between two parts of the circumferential link to enhance stability of the structure.

As per claim 20, Kaplan discloses the prosthesis of Claim 18 however, does not specifically disclose wherein the circumferential link further comprising an axial coupling member disposed between the frond engagement portion and the catheter securement portion. Kaplan discloses wherein the adjacent circumferentially undulating member can be connected to each other by a plurality of connector elements such as axially extending members (61) (fig. 2A) or N-shaped connector elements (figs. 2E-2F) (para [0074]), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). Williams discloses wherein the stent comprises a plurality of undulating rings, and the rings can be attached to each other by links having various shapes, including straight links or non-linear links having curved portions (para [0082]-[0083]). Davis discloses wherein a plurality of connectors (61) is provided to connect the frond (16) to the support section (52) (para [0163], fig. 2G), and the circumferential link (120) may be connected to the frond (16) in a variety of ways, such as by providing one or more connectors (121) (para [0164], fig. 2G). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan, Williams, and Davis, wherein the circumferential link can comprise an axially extending member disposed between the frond engagement portion and the catheter securement portion, similar to the connection structure in the support, to make a secure connection to enhance stability of the Structure.

As per claim 21, Kaplan, Williams, and Davis disclose the prosthesis of Claim 20, however, do not specifically disclose wherein the frond engagement portion and the catheter securement portion are undulating portions that extend circumferentially and out-of-phase with each other. Kaplan discloses wherein the circumferential link has an undulating configuration (para [0116], fig. 2F: circumferential link (120)). Williams discloses wherein the stent comprises a plurality of undulating rings that are connected each other by links, and the links are not limited by any particular length or shape and can be a weld, laser fusion, or similar connection, and welds or laser fusion processes are particularly suited to stent patterns that are out of phase (para [0082]-[0083]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Williams, wherein two portion of the circumferential link (the frond engagement portion and the catheter securement portion) can have an undulating pattern that is out-of-phase with a generally sinusoidal pattern to enhance expandability of the circumferential link structure. In addition, Kaplan does not specifically disclose wherein the axial coupling member connects a trough of the frond engagement portion with a peak of the catheter securement portion. Kaplan discloses wherein the connector members such as the axially extending member (61) in fig.2A link the distal apices of distal apices of the second circumferential undulating member to distal spices of the first circumferential undulating member, or the proximal apices of distal apices of the second circumferential undulating member to proximal spices of the first circumferential undulating member, or like the connecter members such as shown in fig. 2D link the distal apices of distal apices of the second circumferential oriented undulating member to proximal apices of the first circumferential undulating member (para [0074]) and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the axially extending member can connect a trough of the frond engagement portion with a peak of the catheter securement portion, similar to the connecting structure in the support section, to provide proper connection between two parts of the circumferential link to enhance stability of the structure.

------See Supplemental Sheets-----

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Supplemental Sheets: Box V.2: Citations and Explanations:

As per claim 38, Kaplan discloses the prosthesis of Claim 37, Kaplan further discloses the circumferential link comprises a frond engagement portion (para [0116], fig. 2F: circumferential link (120)) , however, does not specifically disclose wherein the circumferential link comprises a catheter securement portion. Kaplan discloses wherein at least one circumferential link connects on proximal of the fronds (para [0017]), and the method comprises a prosthesis and a delivery system (para [0057], fig. 1: prosthesis (10) and a delivery catheter (30)), wherein delivery system comprises a delivery catheter, at least a portion of catheter is positioned in the fronds, and the system also includes a retainer such as cuff for capturing the fronds to prevent them from divaricating from the expandable member as the catheter is advanced through a patient's vasculature (para [0047], fig. 5: cuff (250)). It would have been obvious to one of ordinary skill in the art to use and modify the teaching of Kaplan, wherein circumferential link can comprise the second portion such as a catheter securement portion, located on a proximal side of the first portion that the second portion configured to surround a space that can be occupied by at least a portion of an expansion device, to provide a secure expandable connection between a proximal portion of the prosthesis and a delivery device. In addition, Kaplan does not specifically disclose wherein the circumferential link comprises an axially extending member extending therebetween, Kaplan discloses wherein the support comprises a plurality of axially extending members (61) to connect adjacent serpentine elements (56 and 58) (para [0074], fig. 2A), and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). Williams discloses wherein the stent comprises a plurality of undulating rings, and the rings can be attached to each other by links having various shapes, including straight links or non-linear links having curved portions (para [0082]-[0083]). Davis discloses wherein a plurality of connectors (61) is provided to connect the frond (16) to the support section (52) (para [0163], fig. 2G), and the circumferential link (120) may be connected to the frond (16) in a variety of ways, such as by providing one or more connectors (121) (para [0164], fig. 2G). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan, Williams, and Davis, wherein the connection between two parts of circumferential link can be provided using an axially extending member extending therebetween, like the connection structure in the support between adjacent serpentine elements or the connection structure between the circumferential link and the fronds to make a secure portion to be occupied by a portion of the catheter and to enhance stability of the catheter securement portion.

As per claim 39, Kaplan, Williams, and Davis disclose the prosthesis of Claim 38, however, does not specifically disclose wherein the frond engagement portion and the catheter securement portion are undulating portion that extend out-of-phase. Kaplan discloses wherein the circumferential link has an undulating configuration (para [0116], fig. 2F: circumferential link (120)). Williams discloses wherein the stent comprises a plurality of undulating rings that are connected each other by links, and the links are not limited by any particular length or shape and can be a weld, laser fusion, or similar connection, and welds or laser fusion processes are particularly suited to stent patterns that are out of phase (para [0082]-[0083]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan and Williams, wherein two portion of the circumferential link (the frond engagement portion and the catheter securement portion) can have an undulating pattern that is out-of-phase with a generally sinusoidal pattern to enhance expandability of the circumferential link structure. In addition, Kaplan does not specifically disclose wherein the axially extending member connects a trough of the frond engagement portion with a peak of the catheter securement portion. Kaplan discloses wherein the connector members such as the axially extending member (61) in fig.2A link the distal apices of distal apices of the second circumferential undulating member to distal spices of the first circumferential undulating member, or the proximal apices of distal apices of the second circumferential undulating member to proximal spices of the first circumferential undulating member, or like the connecter members such as shown in fig. 2D link the distal apices of distal apices of the second circumferential oriented undulating member to proximal apices of the first circumferential undulating member (para [0074]) and the circumferential link may comprise a stent or other support structure which is similar to the support structure (para [0117]). It would have been obvious to one of ordinary skill in the art to use and modify the combined teachings of Kaplan in different embodiment, wherein the axially extending member can connect a trough of the frond engagement portion with a peak of the catheter securement portion, similar to the connecting structure in the support section, to provide proper connection between two parts of the circumferential link to enhance stability of the structure.

Claims 1-46 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.